APPLICATION

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FLEXIBLE AND CONFORMABLE EMBOLIC FILTERING DEVICES

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FLEXIBLE AND CONFORMABLE EMBOLIC FILTERING DEVICES

FIELD OF THE INVENTION

The present invention relates generally to filtering devices used when an interventional procedure is being performed in a stenosed or occluded region of a body vessel to capture embolic material that may be created and released into the vessel during the procedure. The present invention is more particularly directed to an embolic filtering device made with an expandable cage possessing good flexibility and bendability, which allows the embolic filtering device to be readily deployed in a bend in a body lumen of a patient.

BACKGROUND OF THE INVENTION

Numerous procedures have been developed for treating occluded blood vessels to allow blood to flow without obstruction. Such procedures usually involve the percutaneous introduction of an interventional device into the lumen of the artery, usually by a catheter. One widely known and medically accepted procedure is balloon angioplasty in which an inflatable balloon is introduced within the stenosed region of the blood vessel to dilate the occluded vessel. The balloon dilatation catheter is initially inserted into the patient's arterial system and is advanced and manipulated into the area of stenosis in the artery. The balloon is inflated to compress the plaque and press the vessel wall radially outward to increase the diameter of the blood vessel, resulting in increased blood flow. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those

skilled in the art, while the above-described procedure is typical, it is not the only method used in angioplasty.

Another procedure is laser angioplasty which utilizes a laser to ablate the stenosis by super heating and vaporizing the deposited plaque. Atherectomy is yet another method of treating a stenosed body vessel in which cutting blades are rotated to shave the deposited plaque from the arterial wall. A vacuum catheter is usually used to capture the shaved plaque or thrombus from the blood stream during this procedure.

In the procedures of the kind referenced above, abrupt reclosure may occur or restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the occurrence of abrupt reclosure and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside the artery across the lesion. The stent can be crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter.

The above non-surgical interventional procedures, when successful, avoid the necessity of major surgical operations. However, there is one common problem which can become associated with all of these non-surgical procedures, namely, the potential release of embolic debris into the bloodstream that can occlude distal vasculature and cause significant health problems to the patient. For example, during deployment of a stent, it is possible that the metal struts of the stent can cut into the stenosis and shear off pieces of plaque that can travel downstream and lodge somewhere in the patient's vascular system. Pieces of plaque material are sometimes generated during a balloon angioplasty procedure and become released into the bloodstream. Additionally, while complete vaporization of plaque is the intended

goal during laser angioplasty, sometimes particles are not fully vaporized and enter the bloodstream. Likewise, not all of the emboli created during an atherectomy procedure may be drawn into the vacuum catheter and, as a result, enter the bloodstream as well.

When any of the above-described procedures are performed in the carotid arteries, the release of emboli into the circulatory system can be extremely dangerous and sometimes fatal to the patient. Debris carried by the bloodstream to distal vessels of the brain can cause cerebral vessels to occlude, resulting in a stroke, and in some cases, death. Therefore, although cerebral percutaneous transluminal angioplasty has been performed in the past, the number of procedures performed has been somewhat limited due to the justifiable fear of an embolic stroke occuring should embolic debris enter the bloodstream and block vital downstream blood passages.

Medical devices have been developed to attempt to deal with the problem created when debris or fragments enter the circulatory system following vessel treatment utilizing any one of the above-identified procedures. One approach which has been attempted is the cutting of any debris into minute sizes which pose little chance of becoming occluded in major vessels within the patient's vasculature. However, it is often difficult to control the size of the fragments which are formed, and the potential risk of vessel occlusion still exists, making such a procedure in the carotid arteries a high-risk proposition.

Other techniques include the use of catheters with a vacuum source which provides temporary suction to remove embolic debris from the bloodstream. However, as mentioned above, there can be complications associated with such systems if the vacuum catheter does not remove all of the embolic material from the bloodstream. Also, a powerful suction could cause trauma to the patient's vasculature.

Another technique which has had some success utilizes a filter or trap

downstream from the treatment site to capture embolic debris before it reaches the smaller blood vessels downstream. The placement of a filter in the patient's vasculature during treatment of the vascular lesion can reduce the presence of the embolic debris in the bloodstream. Such embolic filters are usually delivered in a collapsed position through the patient's vasculature and then expanded to trap the embolic debris. Some of these embolic filters are self expanding and utilize a restraining sheath which maintains the expandable filter in a collapsed position until it is ready to be expanded within the patient's vasculature. The physician can retract the proximal end of the restraining sheath to expose the expandable filter, causing the filter to expand at the desired location. Once the procedure is completed, the filter can be collapsed, and the filter (with the trapped embolic debris) can then be removed from the vessel. While a filter can be effective in capturing embolic material, the filter still needs to be collapsed and removed from the vessel. During this step, there is a possibility that trapped embolic debris can backflow through the inlet opening of the filter and enter the bloodstream as the filtering system is being collapsed and removed from the patient. Therefore, it is important that any captured embolic debris remain trapped within this filter so that particles are not released back into the body vessel.

Some prior art expandable filters vessel are attached to the distal end of a guide wire or guide wire-like member which allows the filtering device to be steered in the patient's vasculature as the guide wire is positioned by the physician. Once the guide wire is in proper position in the vasculature, the embolic filter can be deployed to capture embolic debris. The guide wire can then be used by the physician to deliver interventional devices, such as a balloon angioplasty dilatation catheter or a stent delivery catheter, to perform the interventional procedure in the area of treatment. After the procedure is completed, a recovery sheath can be delivered over the guide wire using over-the-wire techniques to collapse the expanded filter for removal from the patient's vasculature.

When a combination of an expandable filter and guide wire is utilized, it is important that the expandable filter portion remains flexible in order to negotiate the often tortuous anatomy through which it is being delivered. An expandable filter which is too stiff could prevent the device from reaching the desired deployment position within the patient's vasculature. As a result, there is a need to increase the flexibility of the expandable filter without compromising its structural integrity once in position within the patient's body vessel. Also, while it is beneficial if the area of treatment is located in a substantially straight portion of the patient's vasculature, sometimes the area of treatment is at a curved portion of the body vessel which can be problematic to the physician when implanting the expandable filter. If the expandable filter portion is too stiff, it is possible that the filter may not fully deploy within the curved portion of the body vessel. As a result, gaps between the filter and vessel wall can be formed which may permit some embolic debris to pass therethrough. Therefore, the filtering device should be sufficiently flexible to be deployed in, and to conform to, a tortuous section of the patient's vasculature, when needed.

Expandable filters can be provided with some increased flexibility by forming the struts of the filter assembly from relatively thin material. However, the use of thin material often can reduce the radiopacity of the expandable filter, often making it difficult for the physician to see the filter under fluoroscopy during deployment. Conversely, the use of thicker materials, which can promote radiopacity of the expandable filter, usually reduces its flexibility, which may impair the deliverability of the expandable filter within the patient.

What has been needed is an expandable filter assembly having high flexibility and bendability with sufficient strength and radiopacity to be successfully deployed within a patient's vasculature to collect embolic debris which may be released into the patient's vasculature.

SUMMARY OF THE INVENTION

The present invention provides a highly flexible cage (also referred to as a "basket") for use with an embolic filtering device designed to capture embolic debris created during the performance of a therapeutic interventional procedure, such as a balloon angioplasty or stenting procedure, in a body vessel. The present invention provides the physician with an embolic filtering device having high flexibility to be steered through tortuous anatomy, but yet possessing sufficient strength to hold open a filtering element against the wall of the body vessel for capturing embolic debris. An embolic filtering device made in accordance with the present invention is relatively easy to deploy, has good visibility under fluoroscopy, and has good flexibility and is conformable to the patient's anatomy.

An expandable cage made in accordance with the present invention from a self-expanding material, for example, nickel titanium (NiTi) or spring steel, and includes a number of outwardly extending struts capable of expanding from a collapsed position having a first delivery diameter to an expanded or deployed position having a second implanted diameter. A filter element made from an embolic-capturing material is attached to the expandable cage to move between a collapsed position and a deployed position.

The struts of the cage can be set to remain in the expanded, deployed position until an external force is placed over the struts to collapse and move the struts to the collapsed position. One way of accomplishing this is through the use of a restraining sheath, for example, which can be placed over the filtering device in a coaxial fashion to contact the cage and move the cage into the collapsed position. The embolic filtering device can be placed in the patient's vasculature and remain there for a period of time. The filtering device can be attached to the distal end of an elongated member, such as a guide wire, for temporary placement in the vasculature to capture emboli created during an interventional procedure. A guide wire may be

used in conjunction with the filtering device when embolic debris is to be filtered during an interventional procedure. In this manner, the guide wire and filtering assembly, with the restraining sheath placed over the filter assembly, can be placed into the patient's vasculature. Once the physician properly manipulates the guide wire into the target area, the restraining sheath can be retracted to deploy the basket into the expanded position. This can be easily performed by the physician by simply retracting the proximal end of the restraining sheath (located outside of the patient). Once the restraining sheath is retracted, the self-expanding properties of the cage cause each strut to move in a outward, radial fashion away from the guide wire to contact the wall of the body vessel. As the struts expand radially, so does the filter element which will now be maintained in place to collect embolic debris that may be released into the bloodstream as the physician performs the interventional procedure. The guide wire can then be used by the physician to deliver the necessary interventional device into the area of treatment. The deployed filter element captures embolic debris created and released into the body vessel during the interventional procedure.

In one aspect of the present invention, the enhanced flexibility and bendability of the embolic filtering device is achieved through the utilization of a unique cage design having a highly flexible and conformable circumferential member which is adapted to expand and conform to the size and shape of the body vessel. The expandable cage further includes at least one proximal strut having an end connected to a guide wire and the other end attached to the circumferential member. At least one distal strut is attached to the circumferential member and has its other end attached to the guide wire. The filter element is attached to the circumferential member and will open and close as the expandable cage moves between its expanded, deployed position and its unexpanded, delivery position. The circumferential member is self-expanding and is made from a highly flexible material which allows it to conform to the particular size and shape of the body vessel. This high flexibility and

conformability of the circumferential member allows it to deployed in curved sections of the patient's anatomy and other eccentric vessel locations having non-circular shaped lumens. This allows an embolic filtering device made in accordance with the present invention to be deployed in locations in the patient's anatomy which might not be otherwise suitable for stiffer filtering devices. Moreover, due to the high flexibility and conformability of the circumferential member, an embolic filtering device made in accordance with present invention is less likely to create gaps between the filtering element and the wall of the vessel once deployed in the lumen. Therefore, the potential release of embolic debris past the deployed filter can be reduced.

In another aspect of the present invention, bending regions formed on the circumferential member help to actuate the circumferential member between its unexpanded and expanded positions. In one aspect of the present invention, these bending regions are substantially U-shaped bends formed on the circumferential member at various locations along the member. While the circumferential member itself is self-expanding and capable of moving between these positions, the bending regions further enhance the actuation of the circumferential member between these positions. In one particular aspect of the present invention, the proximal strut is attached directly to this bending region. Likewise, a distal strut can be attached to a second bend section. In this fashion, a highly bendable and conformable cage can be produced which should conform to the particular shape of the body vessel once deployed.

In other aspects of the present invention, a pair of circumferential members can be utilized to create the expandable cage which maintains a high degree of bendability and conformability, but yet is sufficiently rigid enough to maintain the filtering element in an expanded position once the filtering device is fully deployed. Still other aspects of the present invention utilize a pair of proximal struts and a pair of distal struts to form a larger expandable cage which still retains good bendability and conformability, yet possesses sufficiently radial strength when deployed to

maintain proper wall apposition between the filter element and the body vessel.

It is to be understood that the present invention is not limited by the embodiments described herein. The present invention can be used in arteries, veins, and other body vessels. Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of an embolic filtering device embodying features of the present invention.

FIG. 2 is a perspective view of the expandable cage which forms part of the embolic filtering device of FIG. 1.

FIG. 3 is an elevational view, partially in cross section, of an embolic filtering device embodying features of the present invention as it is being delivered within a body vessel downstream from an area to be treated.

FIG. 4 is an elevational view, partially in cross section, similar to that shown in FIG. 3, wherein the embolic filtering device is deployed in its expanded position within the body vessel.

FIG. 5 is a perspective view of an alternative embodiment of an expandable cage similar to the cage of FIG. 2 which is attached to a guide wire that extends through the expandable cage to the distal end of the cage.

FIG. 6 is another particular embodiment of an embolic filtering device embodying features of the present invention.

FIG. 7 is an side elevational view of the expandable cage which forms part of the embolic filtering device shown in FIG. 6.

FIG. 8 is a top plan view of the expandable cage of FIG. 7 taken along line 8-8.

FIG. 9 is an end view of the expandable cage of FIG. 7 taken along line 9-9.

FIG. 10 is an alternative embodiment of an embolic filtering device embodying features of the present invention which utilizes a similar expandable cage as shown in FIG. 5.

FIG. 11 is an elevational view, partially in cross-section, of the distal end of the embolic filtering device of FIG. 1.

FIG. 12 is an elevational view, partially in cross-section, of the distal end of the embolic filtering device of FIG. 10.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, in which like reference numerals represent like or corresponding elements in the drawings, FIGS. 1 and 2 illustrate one particular embodiment of an embolic filtering device 20 incorporating features of the

present invention. This embolic filtering device 20 is designed to capture embolic debris which may be created and released into a body vessel during an interventional procedure. The embolic filtering device 20 includes an expandable filter assembly 22 having a self-expanding basket or cage 24 and a filter element 26 attached thereto. In this particular embodiment, the expandable filter assembly 22 is rotatably mounted on the distal end of an elongated (solid or hollow) cylindrical tubular shaft, such as a guide wire 28. The guide wire has a proximal end (not shown) which extends outside the patient and is manipulated by the physician to deliver the filter assembly into the target area in the patient's vasculature. A restraining or delivery sheath 30 (FIG. 3) extends coaxially along the guide wire 28 in order to maintain the expandable filter assembly 22 in its collapsed position until it is ready to be deployed within the patient's vasculature. The expandable filter assembly 22 is deployed by the physician by simply retracting the restraining sheath 30 proximally to expose the expandable filter assembly. Once the restraining sheath is retracted, the self-expanding cage 24 immediately begins to expand within the body vessel (see FIG. 4), causing the filter element 26 to expand as well.

An obturator 32 affixed to the distal end of the filter assembly 32 can be implemented to prevent possible "snowplowing" of the embolic filtering device as it is being delivered through the vasculature. The obturator can be made from a soft polymeric material, such as Pebax 40D, and has a smooth surface to help the embolic filtering device travel through the vasculature and cross lesions while preventing the distal end of the restraining sheath 30 from "digging" or "snowplowing" into the wall of the body vessel.

In FIGS. 3 and 4, the embolic filtering device 20 is shown as it is being delivered within an artery 34 or other body vessel of the patient. Since the embolic filtering device made in accordance with the present invention possesses excellent bendability and flexibility, it will conform well to the shape of the vasculature while allowing the filter assembly to more easily negotiate a curved radius in the patient's

vasculature.

Referring now to FIG. 4, the embolic filtering device 22 is shown in its expanded position within the patient's artery 34. This portion of the artery 34 has an area of treatment 36 in which atherosclerotic plaque 38 has built up against the inside wall 40 of the artery 34. The filter assembly 22 is to be placed distal to, and downstream from, the area of treatment 36. For example, the therapeutic interventional procedure may comprise the implantation of a stent (not shown) to increase the diameter of an occluded artery and increase the flow of blood therethrough. It should be appreciated that the embodiments of the embolic filtering device described herein are illustrated and described by way of example only and not by way of limitation. Also, while the present invention is described in detail as applied to an artery of the patient, those skilled in the art will appreciate that it can also be used in other body vessels, such as the coronary arteries, carotid arteries, renal arteries, saphenous vein grafts and other peripheral arteries. Additionally, the present invention can be utilized when a physician performs any one of a number of interventional procedures, such as balloon angioplasty, laser angioplasty or atherectomy which generally require an embolic filtering device to capture embolic debris created during the procedure.

The cage 24 includes self-expanding struts which, upon release from the restraining sheath 30, expand the filter element 26 into its deployed position within the artery (FIG. 4). Embolic particles 27 created during the interventional procedure and released into the bloodstream are captured within the deployed filter element 26. The filter may include perfusion openings 29, or other suitable perfusion means, for allowing blood flow through the filter 26. The filter element will capture embolic particles which are larger than the perfusion openings while allowing some blood to perfuse downstream to vital organs. Although not shown, a balloon angioplasty catheter can be initially introduced within the patient's vasculature in a conventional SELDINGER technique through a guiding catheter (not shown). The guide wire 28 is

disposed through the area of treatment and the dilatation catheter can be advanced over the guide wire 28 within the artery 34 until the balloon portion is directly in the area of treatment 36. The balloon of the dilatation catheter can be expanded, expanding the plaque 38 against the wall 40 of the artery 34 to expand the artery and reduce the blockage in the vessel at the position of the plaque 38. After the dilatation catheter is removed from the patient's vasculature, a stent (not shown) could be implanted in the area of treatment 36 using over-the-wire techniques to help hold and maintain this portion of the artery 34 and help prevent restenosis from occurring in the area of treatment. The stent could be delivered to the area of treatment on a stent delivery catheter (not shown) which is advanced from the proximal end of the guide wire to the area of treatment. Any embolic debris created during the interventional procedure will be released into the bloodstream and should enter the filter 26. Once the procedure is completed, the interventional device may be removed from the guide wire. The filter assembly 22 can also be collapsed and removed from the artery 34, taking with it any embolic debris trapped within the filter element 26. A recovery sheath (not shown) can be delivered over the guide wire 28 to collapse the filter assembly 22 for removal from the patient's vasculature.

Referring again to FIGS. 1 and 2, the expandable cage 24 includes a pair of self-expanding proximal struts 42 and 44 which help to deploy the filter element 26 and the remainder of the expandable cage. These proximal struts 42 and 44 are coupled to a first circumferential member 46 which is adapted to move from the unexpanded delivery position (FIG. 3) to the expanded deployed position (FIG. 4). A second circumferential member 48 is, in turn, coupled to the first circumferential member 46. The deployment of the first and second circumferential members 46 and 48 results in the filter element 26 being placed against the wall 40 of the artery or other body vessel, even if the lumen of the body vessel is non-circular. A pair of distal struts 50 and 52 connected to the second circumferential member 48 extend distally towards the obturator 32. The first and second circumferential

members 46 and 48 are coupled to, and spaced apart, from each other by short connecting struts 54. It should be appreciated that a single circumferential member could be used to create an expandable cage made in accordance with the present invention. Also, additional circumferential members could be added to create a larger expandable cage. Additionally, while only two proximal struts and distal struts are shown in the cage design of FIGS. 1-5, the cage could also be made with a single proximal and distal strut (see FIGS. 6-10) or additional struts (not shown) could be implemented without departing from the spirit and scope of the present invention.

As can be seen in FIGS. 1 and 2, each circumferential member includes four bending regions 56, 58, 60 and 62 formed on the circumferential member to enhance the performance of the circumferential member to bend as it moves between the unexpanded and expanded positions. In the particular embodiment shown in FIG. 2, each bending region 56-62 is placed on the circumferential member approximately 90 degrees apart. Each of the proximal struts includes a first end 64 attached to the collar 65 which is rotatably mounted to the guide wire 28. Each proximal strut includes a second end 66 connected to one of the proximal bending regions 56 and 58 of the first circumferential member 46. These proximal bending regions 56 and 58 are spaced approximately 180 degrees apart from each other along a circular diameter defined by the expanded circumferential member 46. Each of the distal struts 50 and 52, in turn, has a first end 68 connected to and extending towards the obturator 32 and a second end 70 attached to the distal bending regions 60 and 62 of the second circumferential member 48. These distal bending regions 60 and 62, in turn, are spaced approximately 180 degrees apart from each other and are offset 90 degrees from the proximal bending regions 56 and 58.

Each of the bending regions is substantially U-shaped which help to create a natural bending point on the circumferential member. While the flexibility of the circumferential members is already high, these bending regions only help to increase the ability of the circumferential member to collapse or expand when needed.

In this manner, the shape of the hinge regions creates a natural hinge that helps to actuate the expandable cage between the unexpanded and expanded positions. As can be best seen in FIG. 2, the U-shaped bending regions 54 and 56 are positioned directly opposite the U-shaped portion of the distal bending regions 58 and 60. The positioning of the direction of the U portion also enhances the ability of the circumferential member to bend. These circumferential members 46 and 48, while being quite bendable, nevertheless maintain sufficient radial strength to remain in the deployed position to hold the filter element 26 open in the body vessel for collecting embolic particles which may be entrained in the body fluid.

The shape of the bending regions are shown as substantially U-shaped portions, however, any one of a number of different shapes could also be utilized to create a natural bending point on the circumferential member. For example, a V-shaped region could also be formed and would function similarly to a U-shaped portion to facilitate the collapse and expansion of the circumferential member as needed. Alternative shapes and sizes of the bending regions also could be utilized without departing from the spirit and scope of the invention. Although four bending regions are shown on each circumferential member, it should be appreciated that the number of different bending regions could be increased or decreased as needed. For example, it is possible to utilize only two bending regions, as is shown in the embodiment of the expandable cage of FIG. 6, in order to facilitate bending. Additional bending regions also could be utilized in the event that additional proximal or distal struts are used to form the expandable cage. Moreover, different sizes, shapes and location of the bending regions can be utilized on any circumferential member.

The expandable cage 24 of FIGS. 1 and 2 is shown rotatably mounted to the distal end of the guide wire 28 to allow the entire filtering assembly 22 to remain stationary once deployed in the body vessel. This feature prevents the filtering assembly from rotating in the event that the proximal end of the guide wire is

accidentally rotated by the physician during use. As a result, the possibility that the deployed filtering assembly 22 could be rotated to cause trauma to the wall of the vessel is minimized. Referring specifically to FIGS. 1 and 2, the first end 64 of the proximal struts 42 and 44 are attached to the collar 65 which is rotatably mounted on the guide wire 28 between a pair of stop fittings 72 and 74. The stop fittings 72 and 74 allow the expandable cage 24 to spin on the guide wire but restricts the longitudinal movement of the cage on the guide wire. This particular mechanism is but one way to rotatably mount the expandable cage 24 to the guide wire 28.

The expandable cage is shown in FIGS. 1 and 2 does not include a segment of guide wire which would otherwise extend through the expandable cage 24 to the distal end where the coil tip 76 extends through the obturator 32. In this manner, the elimination of this short segment of guide wire through the expandable cage 24 may help collapse the filter assembly 22 to a smaller delivery profile. The lack of the guide wire segment also may help to increase the flexibility and bendability of the filtering assembly 22 somewhat as it is being delivered through the patient's vasculature.

Referring now to FIG. 5, an alternative version of the embolic filtering device 20 is shown as it is rotatably mounted onto a guide wire 28. In FIG. 5, the filter element has been removed to better show the portion of the guide wire which extends through the expandable cage to the coil tip of the guide wire. In this particular embodiment, a short segment of guide wire 78 is present and extends through the expandable cage 24 and extends through the obturator 32. This particular embodiment of the embolic filtering device functions in the same fashion as the filter device shown and described in FIGS. 1-4. However, a full-length guide wire is utilized in conjunction with this particular embodiment. While this particular embodiment of the filtering device may not be collapsed to a smaller profile as the one shown in FIGS. 1 and 2, nevertheless it has the advantage of a full-length guide wire which allows the physician to manipulate the proximal end of the guide wire in

order to steer the device in the patient's vasculature. The expandable cage 24 would be rotatably mounted on the guide wire as the proximal collar would be placed between two stop fittings located on the guide wire. One benefit from this particular embodiment stems from the ability of the physician to control the proximal end of the guide wire in order to steer the distal coil tip 76 into the desired vessel when delivering the device through the patient's vasculature. The embodiment of the filtering device shown in FIG. 1, while having its own advantages, does not allow the guide wire itself to be rotated at its proximal end of the guide wire to steer the distal coil tip 76 of the guide wire. However, the composite delivery sheath utilized to restrain and maintain the expandable filter in its collapsed position during delivery could be rotated by the physician to steer the coil tip into the desired vessel. In this manner, the proximal end of the delivery sheath could be torqued by the physician to rotate the distal coil wire into the target location. Alternatively, the particular design shown in FIG. 1 could also be modified so that the distal end of the guide wire, rather than being rotatably connected to the cage 24, is permanently attached together. In such a modification, the first ends of the proximal struts 42 and 44 could be simply bonded or otherwise fastened directly to the guide wire such that the expandable cage will rotate as the guide wire is being rotated. This particular emobidment would allow the physician to simply torque the proximal end of the guide wire to steer the distal coil into the desired area of treatment.

Referring now to FIG. 11, one manner in which the distal ends 68 of the distal struts 52 and 50 could be attached to the obturator 32 as shown. As can be seen in FIG. 11, the distal ends 68 are attached to a tubular member 80 which extends into the obturator 32. The ends 68 are attached to the outer surface 82 of the tubular member 80. The filter 26 tapers to a distal end 84 which is, in turn, bonded or otherwise adhesively attached to the outer surface 82 of this tubular member 80. Likewise, at least a portion of the tubular member 80 is in contact with the obturator 32 and is adhesively bonded or otherwise affixed thereto. The inner

surface 86 of the tubular member 80 is in turn attached to a short segment 88 of the guide wire which extends out to the distal coil tip 76. In this manner, the short segment 88 of the guide wire is adhesively bonded or otherwise attached to the inner surface 68 to remain in place. The combination of elements thus form an integral distal end for the filtering assembly which will remain intact during usage.

Referring now to FIGS. 6-9, an alternative embodiment of the embolic filter device 90 is shown which includes an expandable filter assembly 92 with an expandable cage 94. In this particular embodiment, the expandable cage is a modification of the expandable cage 24 shown in FIGS. 1-5. The filter assembly 92 includes the filter member 96 which is utilized to filter the embolic debris in the body vessel and includes a plurality of openings 98 through which the body fluid flows through while the embolic particles remain trapped in the pocket formed by the filter member 96. The filter assembly 92 is also shown attached to a guide wire 100 which has a proximal end (not shown) which extends outside of the patient's body and is manipulated by the physician in order to steer the device into the target area in the patient's vasculature. This particular embodiment 90 is self-expanding, as the other embodiment shown in FIGS. 1-5, and would be kept in a collapsed delivery position through the use of a sheath which would extend over the filter assembly (as is shown in FIG. 3) in order to deliver the device into the target area.

The expandable cage 94 includes a pair of circumferential members 102 and 104 which are connected together by connecting struts 106. This particular embodiment utilizes a single proximal strut 108 and a single distal strut which extends from the second circumferential member 104 to the obturator 112. A distal coil tip 114 extends distally from the obturator 112 and is utilized by the physician to steer the device into the desired body lumen.

The circumferential members 102 and 104 of this particular expandable cage 94 includes only a pair of bending regions 114 and 116 although it is still possible to utilize other bending regions along the circumferential member if desired.

As a result, the use of a single proximal strut 108 minimizes the surface area of struts placed in front of the opening of the filter assembly 92 thus minimizing the chances that emboli could collect on strut areas rather than being forced into the filter member 96. The use of a single distal strut also allows the device to be more flexible in the distal area where flexibility is needed when negotiating tortuous anatomy. It should be appreciated that a single circumferential member could be used in accordance with the present embodiment or additional circumferential members could be utilized to create a longer filtering assembly if desired.

The proximal strut 108 includes one end 118 which is attached to a collar 120 that is rotatably mounted onto the distal end of the guide wire 100. A pair of stop fittings 122 and 124 maintain the collar 120 rotatably mounted to the distal end of the guide wire 100. The other end 126 of the proximal strut 108 is in turn attached to the bending region 114 located on the proximal circumferential member 102. The distal strut 110 includes one end 128 which is attached to the bending region 116 of the second circumferential member 104 with the other end 130 attached to the obturator 112. FIG. 12 shows one particular method for attaching the distal end 130 to the obturator 112. The method of attachment is very similar to the attachment arrangement shown in FIG. 11 in that the distal end 130 is attached to a tubular member 132 having an outside surface 134 and an inner surface 136. A short segment 138 of the guide wire which is attached to the distal coil tip 114 can be adhesively secured or otherwise fastened to the inner surface 136 of the tubular member 132. Likewise, the distal end 130 of the strut 110 is adhesively bonded or otherwise secured to the outer surface 134 of the tubular member 132. The filter member 96 terminates at a distal end 140 which can be bonded both to the outer surface 134 of the tubular member 132 and also to the inner surface of the obturator 112. In this manner, the distal end of the assembly will remain securedly fastened to form an integral unit that will remain intact during usage.

Referring now to FIG. 10, an alternative design to the embodiment of

FIGS. 6-9 is shown in which a short segment 142 of the guide wire extends through the opening of the expandable cage 94 and extends to the distal end where the distal coil tip 114 is located. In this particular embodiment of the embolic filtering device 90, the short segment 142 of the guide wire extends through the expandable cage 94 and performs substantially the same functions as the embodiment shown in FIG. 5. The tubular member 132 (not shown in FIG. 10) can also extend into the expandable cage 94 to help prevent the filter 96 from tangling on the guide wire segment 142 when the cage 94 is collapsed. The use of a guide wire which extends to the distal most end of the device provides good torqueability to the physician when maneuvering the device in the patient's vasculature. It should also be noted that the expandable cage 94 shown in FIGS. 6-9 could also be permanently affixed to the distal end of the guide wire, rather than being rotatably mounted thereto.

The expandable cage of the present invention can be made in many ways. One particular method of making the cage is to cut a thin-walled tubular member, such as nickel-titanium hypotube, to remove portions of the tubing in the desired pattern for each strut, leaving relatively untouched the portions of the tubing which are to form each strut. The tubing may be cut into the desired pattern by means of a machine-controlled laser. The tubing used to make the cage could possible be made of suitable biocompatible material such as spring steel. Elgiloy is another material which could possibly be used to manufacture the cage. Also, very elastic polymers possibly could be used to manufacture the cage.

The strut size is often very small, so the tubing from which the cage is made may have a small diameter. Typically, the tubing has an outer diameter on the order of about 0.020 - 0.040 inches in the unexpanded condition. Also, the cage can be cut from large diameter tubing. Fittings are attached to both ends of the lased tube to form the final cage geometry. The wall thickness of the tubing is usually about 0.076 mm (0.001 - 0.006 inches). As can be appreciated, the strut width and/or depth at the bending points will be less. For cages deployed in body lumens, such as PTA

applications, the dimensions of the tubing may be correspondingly larger. While it is preferred that the cage be made from laser cut tubing, those skilled in the art will realize that the cage can be laser cut from a flat sheet and then rolled up in a cylindrical configuration with the longitudinal edges welded to form a cylindrical member.

Generally, the tubing is put in a rotatable collet fixture of a machine-controlled apparatus for positioning the tubing relative to a laser. According to machine-encoded instructions, the tubing is then rotated and moved longitudinally relative to the laser which is also machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube is therefore cut into the discrete pattern of the finished struts. The cage can be laser cut much like a stent is laser cut. Details on how the tubing can be cut by a laser are found in U.S. Patent Nos. 5,759,192 (Saunders), 5,780,807 (Saunders) and 6,131,266 (Saunders) which have been assigned to Advanced Cardiovascular Systems, Inc.

The process of cutting a pattern for the strut assembly into the tubing generally is automated except for loading and unloading the length of tubing. For example, a pattern can be cut in tubing using a CNC-opposing collet fixture for axial rotation of the length of tubing, in conjunction with CNC X/Y table to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2 or Nd:YAG laser set-up. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coding.

A suitable composition of nickel-titanium which can be used to manufacture the strut assembly of the present invention is approximately 55% nickel and 45% titanium (by weight) with trace amounts of other elements making up about 0.5% of the composition. The austenite transformation temperature is between about 0°C and 20°C in order to achieve superelasticity at human body temperature. The austenite temperature is measured by the bend and free recovery tangent method. The

upper plateau strength is about a minimum of 60,000 psi with an ultimate tensile strength of a minimum of about 155,000 psi. The permanent set (after applying 8% strain and unloading), is less than approximately 0.5%. The breaking elongation is a minimum of 10%. It should be appreciated that other compositions of nickel-titanium can be utilized, as can other self-expanding alloys, to obtain the same features of a self-expanding cage made in accordance with the present invention.

In one example, the cage of the present invention can be laser cut from a tube of nickel-titanium (Nitinol) whose transformation temperature is below body temperature. After the strut pattern is cut into the hypotube, the tubing is expanded and heat treated to be stable at the desired final diameter. The heat treatment also controls the transformation temperature of the cage such that it is super elastic at body temperature. The transformation temperature is at or below body temperature so that the cage is superelastic at body temperature. The cage is usually implanted into the target vessel which is smaller than the diameter of the cage in the expanded position so that the struts of the cage apply a force to the vessel wall to maintain the cage in its expanded position. It should be appreciated that the cage can be made from either superelastic, stress-induced martensite NiTi or shape-memory NiTi.

The cage could also be manufactured by laser cutting a large diameter tubing of nickel-titanium which would create the cage in its expanded position. Thereafter, the formed cage could be placed in its unexpanded position by backloading the cage into a restraining sheath which will keep the device in the unexpanded position until it is ready for use. If the cage is formed in this manner, there would be no need to heat treat the tubing to achieve the final desired diameter. This process of forming the cage could be implemented when using superelastic or linear-elastic nickel-titanium.

The struts forming the proximal struts can be made from the same or a different material than the distal struts. In this manner, more or less flexibility for the proximal struts can be obtained. When a different material is utilized for the struts of

the proximal struts, the distal struts can be manufactured through the lazing process described above with the proximal struts being formed separately and attached. Suitable fastening means such as adhesive bonding, brazing, soldering, welding and the like can be utilized in order to connect the struts to the distal assembly. Suitable materials for the struts include superelastic materials, such as nickel-titanium, spring steel, Elgiloy, along with polymeric materials which are sufficiently flexible and bendable.

The connecting struts utilized to connect one or more circumferential members together are shown generally as straight segments. However, it is possible to utilize non-linear shapes and sizes which may provide additional flexibility and bendability within the patient's anatomy. Additionally, it is possible to make these connecting struts out of materials which are different from the rest of the expandable cage to further increase flexibility if needed. For example, the connecting strut could be made in an S-shape which may provide additional flexibility in certain curved locations in the patient's anatomy. Moreover, the size and width of the strut could be varied from the remaining strut widths and thicknesses in order to promote additional flexibility. In a similar fashion, the bending regions formed on the circumferential members could also be formed with thinner and narrower strut widths than the remaining elements of the cage in order to enhance flexibility at these bending regions.

The polymeric material which can be utilized to create the filtering element include, but is not limited to, polyurethane and Gortex, a commercially available material. Other possible suitable materials include ePTFE. The material can be elastic or non-elastic. The wall thickness of the filtering element can be about 0.00050 -0.0050 inches. The wall thickness may vary depending on the particular material selected. The material can be made into a cone or similarly sized shape utilizing blow-mold technology or dip technology. The openings can be any different shape or size. A laser, a heated rod or other process can be utilized to create to

perfusion openings in the filter material. The holes, would of course be properly sized to catch the particular size of embolic debris of interest. Holes can be lazed in a spinal pattern with some similar pattern which will aid in the re-wrapping of the media during closure of the device. Additionally, the filter material can have a "set" put in it much like the "set" used in dilatation balloons to make the filter element re-wrap more easily when placed in the collapsed position.

The materials which can be utilized for the restraining sheath can be made from polymeric material such as cross-linked HDPE. This sheath can alternatively be made from a material such as polyolifin which has sufficient strength to hold the compressed strut assembly and has relatively low frictional characteristics to minimize any friction between the filtering assembly and the sheath. Friction can be further reduced by applying a coat of silicone lubricant, such as Microglide®, to the inside surface of the restraining sheath before the sheaths are placed over the filtering assembly.

Further modifications and improvements may additionally be made to the device and method disclosed herein without departing from the scope of the present invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.